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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Albone *et al.*

Confirmation No.: To be Assigned

Application No.: 10/687,035

Group Art Unit: To be Assigned

Filed: October 15, 2003

Examiner: To be Assigned

For: ANTIBODIES THAT BIND CELL-
ASSOCIATED CA 125/0772P AND
METHODS OF USE THEREOF

Attorney Docket No.: 6750-214-999

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application. This paper is being filed pursuant to C.F.R. § 1.34.

1. Enclosures accompanying this Information Disclosure Statement are:
 - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
 - 1b. A legible copy of :
 - ☒ Each U.S. patent application publication and U.S. and foreign patent;
 - ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
 - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
 - ☐ all other information or portion which caused it to be listed on the PTO-1449.
 - 1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
 - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114 (filed herewith).

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
☐ enclosed
☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:
☐ enclosed.
☐ to be charged to Jones Day Deposit Account No. 503013.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

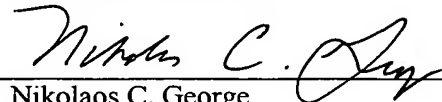
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently

filed herewith.

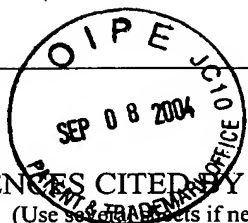
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application, and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- (Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: September 8, 2004


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LIST OF REFERENCES CITED BY APPLICANT

(Use serial numbers if necessary)

ATTY DOCKET NO.

6750-214-999

APPLICATION NO

10/687,035

APPLICANT

Albone *et al.*

FILING DATE

October 15, 2003

GROUP

To be assigned

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	4,921,790	5/1/90	O'Brien			
	A02	5,059,680	10/22/91	Davis <i>et al.</i>			
	A03	5,858,361	1/12/99	Wagner <i>et al.</i>			
	A04	5,976,818	11/2/99	O'Brien			
	A05	6,241,985	6/5/01	Madiyalakan <i>et al.</i>			
	A06	6,468,546	10/22/02	Mitcham <i>et al.</i>			
	A07	6,488,931	12/3/02	Mitcham <i>et al.</i>			
	A08	6,528,253	3/4/03	Mitcham <i>et al.</i>			
	A09	6,699,664	3/2/04	Mitcham <i>et al.</i>			
	A10	6,670,463	12/30/03	Mitcham <i>et al.</i>			
	A11	20020022591	2/21/02	Algate <i>et al.</i>			
	A12	20020119158	8/29/02	Algate <i>et al.</i>			
	A13	20030008299	1/9/03	Algate			
	A14	20030091580	5/15/03	Mitcham <i>et al.</i>			
	A15	20030124140	7/3/03	Bangur <i>et al.</i>			
	A16	20030165504	9/4/03	Retter <i>et al.</i>			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	A17	WO0036107	6/22/00	PCT				
	A18	WO0206317	1/24/02	PCT				
	A19	WO0157207	8/9/01	PCT				
	A20	WO04005470	1/15/04	PCT				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	A21	Bast <i>et al.</i> (1981) "Reactivity of a Monoclonal Antibody with Human Ovarian Cancer" <i>J. Clin Invest</i> 68(5): 1331-37.
	A22	Boshell <i>et al.</i> (1992) "The Product of the Human MUC1 Gene When Secreted by Mouse Cells Transfected With the Full-Length cDNA Lacks Cytoplasmic Tail" <i>Biochem and Biophys Res. Comm</i> 185(1):1-8.
	A23	Frailes <i>et al.</i> (1993) "Purification and Characterization of the CA 125 Tumor-Associated Antigen From Human Ascites" <i>Tumour Biol.</i> 1993;14(1):18-29.
	A24	Gadducci <i>et al.</i> (1992) "The Concomitant Determination of Different Tumor Markers in Patients with Epithelial Ovarian Cancer and Benign Ovarian Masses: Relevance for Differential Diagnosis", <i>Gynecol Oncol.</i> 44(2):147-54.
	A25	Hovig <i>et al.</i> (2001) "CA125: The End of the Beginning" <i>Tumor Bio.</i> 22:345-47.
	A26	Hu <i>et al.</i> (2003) "Discovery and Validation of New Molecular Targets of Ovarian Cancer" <i>Current Opinion in Molecular Therapeutics.</i> 5(6):625-630.
	A27	Kabawat <i>et al.</i> (1983) "Immunopathologic Characterization of a Monoclonal Antibody That Recognizes Common Surface Antigens of Human Ovarian Tumors of Serous, Endometrioid, and Clear Cell Types", <i>Am. J. Clin. Pathol.</i> 79:98-104

A28	Lightenberg <i>et al.</i> (1992) "Cell-Associated Episialin Is a Complex Containing Two Proteins Derived From A Common Precursor" <i>The Journal of Biol. Chem.</i> 267(9):6171-77.
A29	Madiyalakan <i>et al.</i> (1997) "Ovarex MAb-B43.13:IFN-Gamma Could Improve the Ovarian Tumor Cell Sensitivity to CA125-Specific Allogenic Cytotoxic T Cell" <i>Hybridoma</i> 16(1): 41-5.
A30	Maeda <i>et al.</i> (2004) "Solution Structure of the SEA Domain From the Murine Homologue of Ovarian Cancer Antigen CA125 (MUC16)" <i>The Journal of Biol. Chem.</i> 279(13): 13174-13182.
A31	Noujaim <i>et al.</i> (2001) "Induction of CA125-Specific B and T Cell Responses in Patients Injected With MAb-B43.13-- Evidence for Antibody-Mediated Anti-processing and Presentation of CA125 <i>in Vivo</i> " <i>Cancer Biother. Radiopharm</i> 16(3): 187-203.
A32	Nustad <i>et al.</i> (1996) "Specificity and Affinity of 26 Monoclonal Antibodies Against the CA 125 Antigen: First Report From the ISOBM TD-1 Workshop. International Society for Oncodevelopmental Biology and Medicine" <i>Tumour Biol.</i> 17(4): 196-219.
A33	Nustad <i>et al.</i> (2002) "Epitopes on CA 125 From Cervical Mucus and Ascites Fluid and Characterization of Six New Antibodies. Third report from the ISOBM TD-1 workshop" <i>Tumour Biol.</i> 23(5): 303-314.
A34	O'Brien <i>et al.</i> (2001) "The CA125 Gene: An Extracellular Superstructure Dominated by Repeat Sequences" <i>Tumor Bio.</i> 22:348-366.
A35	O'Brien <i>et al.</i> (2002) "The CA125 Gene: A Newly Discovered Extension of the Glycosylated N-Terminal Domain Doubles the Size of This Extracellular Superstructure" <i>Tumor Bio.</i> 23:154-169.
A36	Saga <i>et al.</i> (1990) "Construction of an Immunoradiometric Assay for Ovarian Cancer Antigen CA125 Recognizing Different Antigenic Determinant" <i>ACTA Obstet Gynecol. Scand.</i> 69(2):175-81.
A37	Saga <i>et al.</i> (1990) "An Antibody-Tumor Model for the Targeting of CA125-Producing Gynecologic Malignancies" <i>Jpn J. Cancer Res.</i> 81(11):1141-48.
A38	Yin <i>et al.</i> (2001) "Molecular Cloning of the CA125 Ovarian Cancer Antigen" <i>The Journal of Biol. Chem.</i> 276(29):27371-375.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.